

Clinical trials of ximelagatran

TrialResults-center www.trialresultscenter.org

1 atrial fibrillation

| Trial | Treatments | Patients | Trials design and methods |
|--|--|---|--|
| ximelagatran vs warfarin standard dose | | | |
| SPORTIF V , 2005 n=1960/1962 follow-up: 20 months | ximelegatran 36 mg twice daily versus warfarin standard dose(target INR 2-3) | One or more stroke risk factor in addition to atrial fibrillation.High risk patients with non valvular atrial fibrillation. | Parallel groups Double blind north america |
| SPORTIF II (ximelagatran vs warfarin standard dose) , 2002 n=187/67 follow-up: 16 weeks | ximelegatran 20,40,60 mg twice daily versus warfarin standard dose(target INR 2-3) | Medium to high risk patients with chronic non valvular atrial fibrillation. | Parallel groups Open Europe ,USA |
| SPORTIF III , 2003 n=1704/1703 follow-up: 17.4 months | ximelagatran 36 mg twice daily versus warfarin standard dose (target INR 2-3) | One or more stroke risk factor in addition to AF.High risk patients with non valvular atrial fibrillation. | Parallel groups Open europe,asia,australasia |

More details and results :

- antithrombotics for atrial fibrillation in primary prevention of thromboembolic events at <http://www.trialresultscenter.org/go-Q57>
- direct antithrombins for atrial fibrillation in all type of patients at <http://www.trialresultscenter.org/go-Q368>
- direct oral anticoagulant (DAO) for atrial fibrillation in all type of patients at <http://www.trialresultscenter.org/go-Q391>

References

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SPORTIF II (ximelagatran vs warfarin standard dose), 2002:

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SPORTIF III, 2003:

Olsson SB Stroke prevention with the oral direct thrombin inhibitor ximelagatran compared with warfarin in patients with non-valvular atrial fibrillation (SPORTIF III): randomised controlled trial. Lancet 2003 Nov 22;362:1691-8 [14643116]

2 acute coronary syndrome

| Trial | Treatments | Patients | Trials design and methods |
|--|--|---|----------------------------------|
| ximelagatran vs placebo | | | |
| ESTEEM , 2003 n=1245/638 follow-up: 6 months | oral ximelagatran at doses of 24 mg, 36 mg, 48 mg, or 60 mg twice daily versus placebo | patients who had had recent ST-elevation or non-STelevation myocardial infarction | Parallel groups double-blind |

More details and results :

- antithrombotics for acute coronary syndrome in all type of patients at <http://www.trialresultscenter.org/go-Q24>
- anticoagulant for acute coronary syndrome in All ACS (including AMI) at <http://www.trialresultscenter.org/go-Q167>
- direct factor Xa inhibitors for acute coronary syndrome in all type of patients at <http://www.trialresultscenter.org/go-Q345>
- antithrombotics for acute coronary syndrome in patients with a recent ACS at <http://www.trialresultscenter.org/go-Q387>
- direct oral anticoagulant (DAO) for acute coronary syndrome in all type of patients at <http://www.trialresultscenter.org/go-Q480>

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3 thrombosis prevention

| Trial | Treatments | Patients | Trials design and methods |
|--|--|--|--|
| ximelagatran vs Dalteparin | | | |
| METHRO I , 2002 n=103 follow-up: 69 days | Melagatran 14 mg s.c. immediately before surgery, melagatran at 20.00 hours, then ximelagatran 624 mg orally b.d. for 69 days versus Dalteparin 5000 IU o.d., started evening before surgery for 69 days | adults undergoing hip or knee replacement | parallel group open Swedish |
| METHRO II , 2002 n=1495/381 follow-up: 710 days | Melagatran 13 mg s.c. immediately before surgery, melagatran same day, then ximelagatran 824 mg orally b.d. for 710 days versus Dalteparin 5000 IU o.d., started evening before surgery for 710 days | undergoing hip or knee replacement | Parallel groups double-blind |
| ximelagatran vs Enoxaparin | | | |
| Platinum (Colwell) , 2003 n=906/910 follow-up: 712 days | Ximelagatran 24 mg orally b.d., starting at least 12 h after surgery for 712 days versus Enoxaparin 30 mg s.c. b.d., starting at least 12 h after surgery for 712 days | adults undergoing hip replacement | parallel group double-blind USA, Canada, Israel, Mexico, Argentina, South Africa |
| METHRO III , 2002 n=2788 follow-up: 811 days | Melagatran 3 mg s.c. 412h after surgery, then ximelagatran 24 mg orally b.d. for 710 days versus Enoxaparin 40 mg s.c. o.d. 12 h before surgery for 710 days | hip or knee replacement | double-blind Europe, South Africa |
| Phase II (Heit) , 2001 n=600 follow-up: 612 days | Ximelagatran 8, 12, 18 or 24 mg orally b.d., at least 12 h after surgery for 612 days versus Enoxaparin 30 mg s.c. b.d., starting at least 12 h after surgery for 612 days | adults (age > 18 years and weight at least 40 kg) undergoing knee replacements | parallel group double-blind North American |
| EXPRESS , 2003 n=2835 follow-up: 811 days | Melagatran 2 mg s.c. up to 30 min before surgery, then melagatran 3 mg at least 8 h after surgery, then ximelagatran 24 mg orally b.d. for 811 days versus Enoxaparin 40 mg s.c. o.d., starting 12 h before surgery for 811 days | hip or knee replacement | parallel group double-blind Europe |

More details and results :

- antithrombotics for thrombosis prevention in orthopedic surgery at <http://www.trialresultscenter.org/go-Q37>
- antithrombotics for thrombosis prevention in elective major knee surgery at <http://www.trialresultscenter.org/go-Q38>
- antithrombotics for thrombosis prevention in elective hip replacement at <http://www.trialresultscenter.org/go-Q39>
- direct antithrombins for thrombosis prevention in orthopedic surgery at <http://www.trialresultscenter.org/go-Q185>

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4 venous thrombosis

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|--|
| ximelagatran vs discontinuation | | | |
| THRIVE III , 2003 n=612/611 follow-up: 18 months | ximelagatran 24 mg twice daily for 18 months versus placebo for 18 months | patients with venous thromboembolism who had undergone six months of anticoagulant therapy | Parallel groups double blind 18 countries |
| ximelagatran vs placebo | | | |
| Schulman (subgroup) , 2003 n=NA follow-up: 18 months | extended treatment with Ximelagatran 24mg twice daily after initial anticoagulant treatment for 6 months versus placebo (initial anticoagulant treatment for 6 months) | study subgroup of patients with active cancer in the previous 5 years treated for DVT or pulmonary embolism for 6 months without recurrence | Parallel groups single blind and outcome ass. |
| THRIVE 3 , 2003 n=612/611 follow-up: | ximelagatran (24 mg) versus placebo | patients with venous thromboembolism who had undergone six months of anticoagulant therapy | |
| ximelagatran vs LMWH/VKA | | | |
| Fiessinger , 2005 n=NA follow-up: | ximelagatran 36 mg twice daily versus subcutaneous enoxaparin, 1 mg/kg twice daily, for 5 to 20 days followed by warfarin adjusted to maintain an international normalized ratio of 2.0 to 3.0. | patients with acute deep vein thrombosis | double blind |
| ximelagatran (without LMWH) vs LMWH/VKA | | | |
| THRIVE I , 2003 n=NA follow-up: | oral ximelagatran (24, 36, 48 or 60 mg twice daily) for 2 weeks versus dalteparin and warfarin for 2 weeks | Patients with acute DVT | |

More details and results :

- antithrombotics for venous thrombosis in all type of patients at <http://www.trialresultscenter.org/go-Q101>
- antithrombotics for venous thrombosis in patients with cancer at <http://www.trialresultscenter.org/go-Q103>
- antithrombotics for venous thrombosis in secondary prevention of VTE at <http://www.trialresultscenter.org/go-Q149>
- direct factor Xa inhibitors for venous thrombosis in all type of patients at <http://www.trialresultscenter.org/go-Q372>

- direct oral anticoagulant (DAO) for venous thrombosis in all types of patients at <http://www.trialresultscenter.org/go-Q505>
- antithrombotics for venous thrombosis in secondary prevention - 2 at <http://www.trialresultscenter.org/go-Q682>

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